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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,334	08/13/2001	Michael L. Boyer II	8932-543	6084

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EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 07/29/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

EC

<b>Office Action Summary</b>	Application No. 09/927,334	Applicant(s) BOYER ET AL.	
	Examiner Paul B. Prebilic	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 May 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 1-7 and 27-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                    | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6, 10</u> | 6) <input type="checkbox"/> Other:  |

***Election/Restrictions***

Claims 1-7 and 27-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11 filed May 8, 2003.

Applicant's election with traverse of Species B in Paper No. 11 is acknowledged. The traversal is on the ground(s) that the restriction requirement fails to identify all the figures applicable to claims 8-26. This is not found persuasive because the figure numbers were used to identify species not serve as a means to set forth the entire disclosure of what might fall within the claim scope. Moreover, upon further review, the embodiment of Figures 19 and 20 constitute a separate and patentably distinct species such that claim 26 should have been identified therewith and withdrawn. However, since it was not clear that claim 26 is mutually exclusive of the embodiment claimed in claims 8-25, the Examiner has not made a new requirement with respect thereto. The Examiner reserves the right to make a new restriction requirement if it becomes more burdensome to examine both species together due to Applicant's future amendment(s).

The requirement is still deemed proper and is therefore made FINAL.

***Information Disclosure Statement***

The information disclosure statement filed March 8, 2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that

portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

A search was made to determine if these 83 documents were being stored in a separate location from that of the transmittal, but no such copies could be found.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to claims 8-25, on line 5 of claim 8, it is unclear how the "partially demineralized region" is related to the unitary body in a structural sense. It is unclear what element, if any, is partially demineralized. For this reason, claim 8 and its dependent claims are considered to be indefinite.

With regard to claims 9 and 20, it is unclear how and where the fastener holes are oriented with respect to the other feature of the plate, and thus, the limitation is considered indefinite.

With regard to claim 10, line 2, it is unclear if the first at least partially demineralized region is related to the other demineralized region set forth in base claim 8.

With regard to claim 11, the language "across the entire length" is confusing since "across" denotes a width when a longitudinal axis has been defined and "along" denotes a length. For this reason, the Examiner will interpret this language as further defining the "at least one partially demineralized region" and that this region extends across the width of the device.

With regard to claim 13, it repeats a limitation set forth in claim 10 even though it depends indirectly therefrom; note that the "first at least partially demineralized region" limitation is repeated.

With regard to claim 10 to 16, it is unclear if the first and second regions of partially demineralized regions are subsets of the at least "one partially demineralized region" of claim 8 or not. The Examiner will interpret them as subsets thereof when evaluating the claim on their merits.

With regard to claim 17, the claim language is confusing since the width should inherently be the thinness of the body so it is unclear what is being modified by the claim language. Furthermore, there are two widths set forth so it is unclear which is being referred to and modified in the claim.

With regard to claim 25, it is unclear why "a first width" is being claimed since one was set forth in base claim 8. Therefore, it is unclear whether this width is intended to further modify the "first width" of claim 8 or to present a new width. The former interpretation will be used when evaluating the claim language.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 8 and 17-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Boyd et al (US 6,206,923). Boyd anticipates the claim language where the first width as claimed is in the ends with ridges (18, 19, 20, 21) or wall (201) of Boyd; see Figures 1, 10(a), and 10(b) as well as column 2, lines 13-27, column 3, lines 21-59 and column 6, lines 20-46.

Claims 8-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Sybert et al (US 2002/0107570) where the first width is at the ends and the second width is in the middle portion of Sybert's device; see Figures 1b and 1c as well as paragraphs 33, 38, 39, and 43. It is noted that the ends are demineralized and can be said to be transverse to the central longitudinal axis to the extent required by some of the dependent claims.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 3738

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-12 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyd et al (US 6,206,923) in view of Anderson et al (US 6,458,158). Boyd meets the claim language but fails to disclose fastener holes therein. However, Anderson teaches that fastener holes were known to join components together in similar bone implants; see element (5) of Figure 28. Therefore, it would have been obvious to form fastener holes and pins, as taught by Anderson, in the Boyd device for the same reasons that Anderson does the same, in order to reinforce the mineralized regions, and in order to hold the mineralized regions together.

Claims 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyd et al (US 6,206,923) alone.

With regard to claim 21, Boyd discloses all the features claimed but lacks the generally dogbone shape as claimed. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to shape the implant in a generally dogbone shape because Applicants have not disclosed that the dogbone shape provides some advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicants' invention to perform equally well because the ends would also provide enlarged portions to prevent movement thereof. Instead of the ridges, the dogbone ends would provide the means to prevent movement. Therefore, it would have been an obvious matter of design choice to modify Boyd to obtain the invention as specified in the claims.

Art Unit: 3738

With regard to claims 21-25, Boyd et al fails to disclose the size dimensions for the device thereof, but it is clear that both Boyd and the claimed invention are designed for implantation in a human being; Applicant is directed to see MPEP 2144.04, which is incorporated herein by reference.

*"In Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device."*

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boyd et al (US 6,206,923 in view of Tormala et al (US 5,084,051). Boyd meets the claim language as set forth in the Section 102 rejection above but fails to disclose slits in the first width region as claimed. However, Tormala teaches that it was known to put slits in similar bone implants to facilitate flexing in the rigid portions of the implant; see Figure 3 and column 10, lines 44-54. Therefore, it is the Examiner's position that it would have been prima facie obvious to put slits in the Boyd first width portions in order to facilitate flexing in those regions as taught by Tormala.

### **Conclusion**

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.



Art Unit: 3738

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.

A handwritten signature in black ink, appearing to read "Paul Prebilic", with a stylized flourish extending from the end.

Paul Prebilic  
Primary Examiner  
Art Unit 3738